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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,986	11/21/2003	Mang Yu	21865-002001 / 6502	3664

20985 7590 05/18/2010

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
05/18/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/718,986	YU ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,32-34,47,50,54,57,58,61-74,76-80,82-101 and 108-110* is/are pending in the application.

4a) Of the above claim(s) *50,54,57,58 and 82-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,32-34,47,61-74,76-80,94-101 and 108-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/27/07, 7/22/09 & 10/27/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

1. Amendment filed 3/1/2010 is acknowledged. Claims 1-3, 6, 32-34, 47, 50, 54, 57-58, 61-74, 76-80, 82-93, 94-101 & 108-110 are present in this application.

Claims 1-3, 6, 32-34, 47, 61-74, 76-80 & 94-101 & 108-110 corresponding to the elected invention are under consideration in this Office Action.

2. **Claims withdrawn**:

Claims 50, 54, 57-58 & 82-93 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant's arguments filed 3/1/2010 have been considered and not found to be persuasive. The reasons are discussed following the rejection(s).

4. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

5. ***Written Description***

Claims 1-3, 6, 32-34, 47, 61-74, 76-80 & 94-101 & 108-110 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn in view of Applicants' persuasive arguments and amendment to claims filed 3/1/2010.

6. ***Enablement Rejection***

Claims 1-3, 6, 32-34, 47, 61-74, 76-80 & 94-101 & 108-110 rejected under 35 U.S.C. 112, first paragraph, is withdrawn in view of Applicants' persuasive arguments and amendment to claims filed 3/1/2010.

7. ***Pharmaceutical composition***

Claims 47, 72-73 & 76-79 rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to the composition comprising a compound consisting of an 'anchoring domain' and a 'therapeutic domain', wherein 'anchoring domain' is selected from the sequence of SEQ ID NO: 3, 4 5 or 7, and wherein the 'therapeutic domain' is selected from SEQ ID NO: 8 or 9.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988) **[** *Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

It is neither taught nor data provided for using the specific fusion protein construct in pharmaceutical compositions for the treatment and or prevention of any of the diseases or disorders or infections. There is no evidence presented that specific fusion protein construct(??) is associated with any of the known diseases or disorders or infections or can be treated or prevented by administering the specific fusion protein construct(??). Without such a data or evidence, claims to pharmaceutical composition comprising specific fusion protein construct(??), would amount to a composition or potential drug for treatment for any disorder or disease or infection, which is not enabled. Given the lack of direction or guidance and the nature of the invention, obtaining such a composition for one of skill in the art would be highly unpredictable. This is because the specific fusion protein construct(??) when associated with a particular disease or disorder or infection would be expressed differentially. Manipulating or controlling these levels depends upon the disease or disorder or infection, and may not always be controlled by supplementing with such a specific fusion protein construct(??) composition. Further, no guidance in provided, pertaining to the fate of the administrated specific fusion protein construct(??) *in vivo*.

Since it is not routine in the art to engage in *de novo* experimentation to prepare numerous compositions where the expectation "of success is unpredictable", the skilled artisan would require additional guidance, specific to individual disorder or disease or infection, in order to make and use pharmaceutical compositions in a manner reasonably commensurate with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Arguments:

Applicants argue that in this instance, the specification teaches the construction of compounds containing two well-known, well-characterized domains: a sialidase domain, and a GAG-binding domain. The specification teaches that the sialidase catalytic domain is a suitable for treating a variety of respiratory ailments in which infection is triggered via sialic acid receptors on a target epithelial cell surface. The specification further teaches that once the sialic acid receptor is cleaved, a pathogen, such as influenza virus, whose entry is mediated via these receptors, is unable to do so (page 20, lines 28-29; page 22, lines 12-18). The specification also teaches that a GAG-binding domain is a suitable domain to anchor the sialidase to the epithelial cells, which are ubiquitous expressors of heparin and heparan sulfate (types of GAGs) on the cell surface (page 13, lines 1015; page 21, line 23 to page 22, line 11).

The question that goes to enablement is whether by following these teachings, one of skill in the art can (1) construct a compound containing a sialidase domain and a GAG- binding anchoring domain; and (2) test its ability to prevent or treat pathogenic infection in a suitable assay. The specification has provided ample teachings to be able to do so. No actual working examples are necessary.

As indicated above the specific construct may have pharmaceutical use, however, no data is provided to support the fact the fusion construct is effective in controlling influenza or other viral infections. The rejection is therefore maintained.

New arguments (3/1/2010):

Applicants' important new arguments are based upon the affidavit – declaration pursuant to 37 CFR 1.132 of Fang Fang filed 12/22/2009 describing construction and testing a human sialidase-GAG-binding fusion protein (compound I) using standard molecular cloning method. Table 1 shows the results of cell protection assays conducted using Compound 1; Letters in bold describe the influenza strain used in the assay.

As may be seen from the Table that the cell protection of various influenza strains varied from 12%-51%, and therefore fail to protect at a reasonable level in order the specific fusion protein construct be classified as a pharmaceutical

composition capable of preventing an infection. This is because the composition failed to protect infections in 49%-88% of the cases. This is in spite of the fact that the fusion construct was specific as defined by compound I. In claim 1, for example, the fusion construct is not specific and comprises any bacterial/human sialidase or an active fragment thereof and GAG-binding amino acid sequence of SEQ ID NO: 2, 4, 5, 6 or 7, leading to high level of unpredictability in controlling the infection. The rejection is therefore maintained.

8. Claims 99-101 & 108-110 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 6, 32-34, 61-65. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Irrespective of how the claims are directed to either to a compound or an isolated polypeptide, both are fusion constructs comprising the same or substantially similar elements - hence substantial duplicate of each other.

9. ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6, 32-34, 47, 61-74, 76-80 & 94-101 & 108-110 are provisionally rejected under the judicially created doctrine of double patenting over claims 141-147, 149, 151, 162-169 & 171 of copending Application No. 10/939,262. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The instant claims are directed to a genus of protein-based compositions comprising a compound (fusion protein) that comprises: at least one [1]therapeutic domain having extra cellular activity which may be catalytic or inhibitory and that can prevent infection of target cell; and one [2]anchoring domain which may be a binding domain (*see* specification pages 12-14 for the instantly stated definitions) and that can bind at or near the surface of the target cell. The claims of the copending application are drawn to a fusion protein comprising catalytic domain of sialidase of SEQ ID NO: 16 and an anchoring domain. The instant claims are broader genus composition claims comprising a therapeutic domain (or catalytic domain) and an anchoring domain (or binding domain) and comprises the species claims in the copending application. Since a species anticipates the genus [& genus obviates a species], the copending species claims of U.S. Serial No. 10/939,262 anticipate the instantly claimed generic claims.

Applicants argue that without addressing its merits or conceding its propriety, this rejection will be addressed as appropriate upon indication that there is allowable subject matter in one or both applications.

The rejection is therefore maintained.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached at (571) 272 0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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May 11, 2010